Council for Responsible Nutrition
1875 Eye Street, N.W., Suite 400
Washington, D.C. 20006-5409
(202) 872-1488 • Fax (202) 872-9594
www.crnusa.org

August 30, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 02N-0278, Prior Notice Requirements, Implementation of Bioterrorism Act of 2002

The Council for Responsible Nutrition (CRN) is submitting these initial comments on the prior notice requirements of the Bioterrorism Act of 2002, on behalf of its members in the dietary supplement industry. CRN represents a broad spectrum of the industry ranging from ingredient suppliers to finished product manufacturers, including both brand name products and private label products. Our member companies market their products in all distribution channels, including the mass market, natural food stores, multilevel marketing, and mail order. Our supplier members include companies that make or market all classes of ingredients incorporated into dietary supplements, including vitamins and minerals, amino acids, botanical ingredients, specialty products, and excipients.

CRN's member companies are committed to fully evaluating their procedures with regard to helping ensure that their facilities and products are secure from potential bioterrorism threats.

Our members' concerns about prior notice requirements for imported products are the same ones generally expressed by numerous associations in the conventional food industry. Some of these are summarized below.

- Need for seamless integration with existing import requirements. CRN understands that FDA is working closely with other agencies including the Customs Service and USDA in an attempt to coordinate existing requirements with the new FDA prior notice requirements of the Bioterrorism Act of 2002. We wish to underscore the critical importance of ensuring that the new requirements do not create a barrier to trade, in terms of our obligations to trading partners, or create a backlog of shipments at points of entry that would be detrimental to ingredients or products that may be delayed for administrative reasons (as opposed to being held due to safety concerns).

02N-0278 C 6

- Need for electronic linkage among import data systems. CRN encourages the agency, as we understand it is already doing, to make every effort to enhance electronic capabilities to permit linkage of the various import notifications required for a food or dietary supplement product or ingredient.

- Need for immediate FDA response to prior notices. CRN joins others in the food industry in requesting that FDA ensure that acknowledgement of prior notices be electronic and immediate.

- Need for 24-hour daily operation. In order for the prior notice requirements to be effectively implemented without blocking the flow of trade, CRN agrees with others in the food industry that it will be essential for FDA port operations to be active 24 hours a day seven days a week.

- Minimum time required for prior notice. FDA should take into account air, truck, and train shipments as well as shipments by sea, in determining the minimum time required for the prior notice of import. CRN joins other food associations in urging that the shortest possible time be specified, in order to accommodate the realities of each situation and permit needed ingredients and products to flow through the import and distribution process in a timely manner. The minimum time required will be especially critical for air freight, truck and train shipments that currently arrive at import points within a few hours of departing from their point of origin. There should also be flexibility sufficient to accommodate unavoidable last-minute changes necessary to accommodate inclement weather, interruptions in supply that may necessitate changing the intended makeup of the shipment, and other unforeseen circumstances.

- Who submits the prior notice? CRN shares the view of other food industry associations that in most cases the party responsible for providing the prior notice will be the "Principal", usually the importer of record. These terms are defined in existing provisions administered by other agencies, including Customs. FDA is encouraged to permit some degree of flexibility regarding the party responsible for providing the prior notice.

- Identification of grower, "if known." In the food industry generally, and also in the dietary supplement industry, the grower of a commodity product most often will not be known. The Act requires that the grower be identified as part of the information required in the prior notice, "if known within the specified period of time that notice is required to be provided." CRN urges FDA to provide appropriate flexibility regarding this requirement, to recognize that in many or most cases it will not be feasible to know the grower, and to provide that prior notices that are otherwise acceptable will not be held up solely because the grower's identity is not known.

Thank you for the opportunity to submit initial comments on issues relating to the implementation of the requirements of the Bioterrorism Act of 2002. CRN and its members look forward to working with FDA to facilitate timely implementation and will avail themselves of every opportunity for interaction and comment as this process moves forward, in order to provide the agency with adequate information needed to address the many concerns that will arise. We will be pleased to respond to any specific questions FDA may have regarding the dietary supplement industry, to the best of our ability.

Sincerely,

A Dickinson

Annette Dickinson
Vice President, Scientific & Regulatory Affairs